

REMARKS

This Response is to the Final Office Action of May 12, 2009 and in furtherance of the telephone interview conducted on June 24, 2009. Claims 1, 5 and 6 have been amended. Support for these amendments is found at least at Fig. 1 and paragraph [0025] of U.S. Publication 2004/0104271 (the present application). Claims 7 to 13 have been added. No new matter has been added by these amendments or new claims. Applicants have submitted a Request for Continued Examination and a Supplemental Information Disclosure Statement in connection with this Response. Please charge Deposit Account No. 02-1818 for the Request for Continued Examination and any other amounts due in connection with this Response.

Claims 1 and 3 to 6 have been rejected under 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 6,671,563 to Engelson et al. ("*Engelson*").

During the interview, Applicants' representative and the Examiner discussed *Engelson* in view of proposed amendments similar to those made to the independent claims herein. This Response presents reasons why the present claims are patentably distinguished over *Engelson*. Additionally, as set forth below, Applicants have added dependent claims 7 to 13, which also include steps that are clearly absent from *Engelson*.

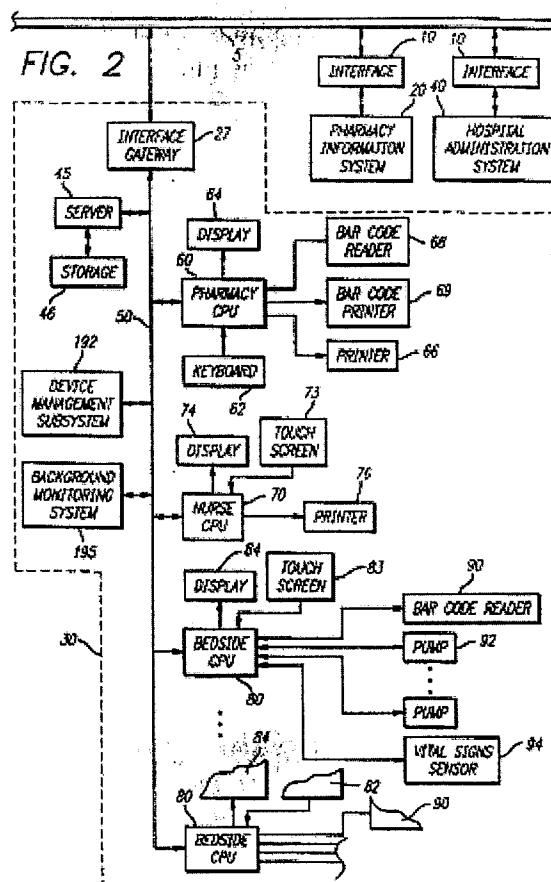
Engelson discloses a care management system including a barcode reader that reads a barcode 175 on a patient ID bracelet and a barcode 182 on a drug container. (See *Engelson*, column 13, lines 25 to 32). The information on the barcode 182 of the drug container, however, is not communicated and downloaded to the medical delivery device. Instead, the information from the drug container is analyzed by a medication administration management software module 110 to determine whether there is a discrepancy between the information read and pre-stored information. (See *Engelson*, column 13, lines 49 to 60). When the medication administration management software module 110 completes its analysis, the care management system of *Engelson* automatically downloads configuration parameters from the pharmacy CPU into a local area network, into the bedside CPU and then into the medical delivery device. (See *Engelson*, column 14, lines 4 to 13).

The Office Action focused on col. 13, lines 35 to 56 of *Engelson*, which state:

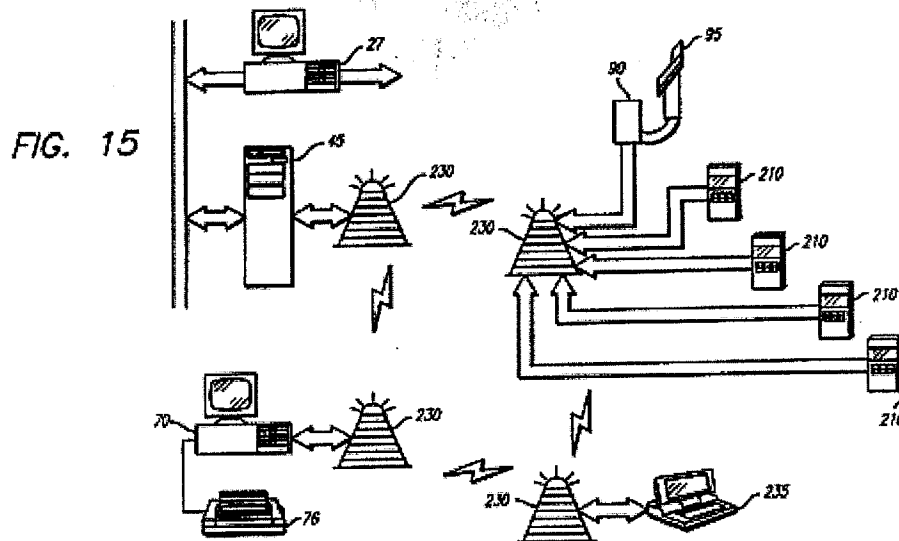
Yet another embodiment of the care management system 30 local area network 50 configuration is shown in FIG. 15. In this configuration, the *ethernet cabling* connecting the pharmacy CPU, the nurse station nursing CPU 70 and bedside

CPUs and clinical devices *is eliminated entirely*. Each hardware element, comprising the file server, nursing CPU 70, pharmacy CPU 60 and bedside CPUs 80 and *clinical devices and/or barcode readers is connected to an RF transmitter/receiver 230*. In this manner, all of the information is transmitted throughout the local area network 50 by way of radio transmission rather than by using costly network cabling. *Such a system would additionally allow for the use of portable computers 235 having RF transmitter/receivers 230 that could then be carried with physicians, nurses or technicians as they circulate through the institution. With this configuration, caregiving personnel could access the care management system either spontaneously or upon notification of an alert no matter where they were in the institution at any given time.* Such a system would be particularly useful in a large institution where caregiving personnel are likely to be responsible for many hospital beds or when personnel are out of the area or off the floor. [Emphasis added].

This above passage describes an embodiment that eliminates the ethernet wiring connecting the components in the care management system 30 of Fig. 2 of *Engelson*, reproduced below, and provides an RF transmitter with each of its devices to enable wireless communication.



Regarding the personal computer 235, referring to Fig. 15, reproduced below, *Engelson* merely discloses that “[c]aregiving personnel could access the care management system either spontaneously or upon notification of an alert no matter where they [are] in the institution at any given time.” See *Engelson*, col. 13, lines 35 to 56.



Engelson simply generically suggests the ability of a physician to access the care management system 30, without providing any detail as to how the personal computer would function in relation to the care management system 30 or in relationship to any of the clinical devices illustrated in Fig. 2 of *Engelson*.

Claim 1, on the other hand, includes providing a handheld computing device with *a housing that is readily portable and directable via single hand operation, the housing carrying each of: means for reading the prescribed medication data and medication delivery instruction from the first label and patient data from the second label*, means for storing the data and instruction, and means for communicating data and instruction to other electronic devices; the handheld computing device **reading** the prescribed medication data and medication delivery instruction from the first label and storing the prescribed medication data and medication delivery instruction; the handheld computing device **reading** the patient data from the second label and storing the patient data; the handheld computing device comparing the stored prescribed medication data to the stored patient data and confirming a match between the stored prescribed medication data and the stored patient data; the handheld computing device communicating the stored medication delivery instruction from the first label to a medication

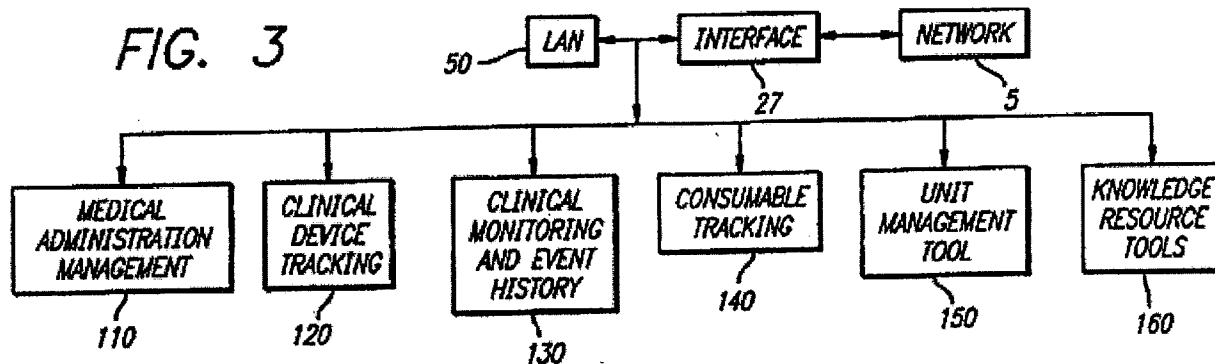
delivery device; and the medication delivery device storing the medication delivery instruction and delivering the medication to the patient.

The portable computer 235 of *Engelson* is just that, a computer. As such, one of ordinary skill in the art would not think that computer 235 has means for **reading** prescribed medication data and medication delivery instructions from a first label and patient data from a second label. Instead, the bar code reader 90 in *Engelson*, which is part of the care management system 30, is disclosed as communicating by hardwire or wirelessly with the bedside CPU 30. The bar code reader 90 is not disclosed as having any operational interaction whatsoever with personal computer 235. If computer 235 were intended to read bar code data, bar code reader 90 is redundant and unnecessary. But that is not the case. *Engelson* requires a bar code reader and thus strongly indicates that computer 235 is not intended to read bar code labels.

Portable computers typically have a top that opens to expose a video monitor. Without opening the top, the computer is useless. When opened, the laptop computer is not evenly balanced and therefore is not readily directable towards a readable target as covered in the claims. The above distinctions are even more accentuated by the clarification in the claims which requires that the handheld computing device be readily portable and directable via single hand operation. As is well understood, laptop computers, especially the very generally described laptop computer of *Engelson* are typically not readily portable and directable via one hand, and certainly not to the degree required to easily manipulate a bar code scanner relative to a bar code.

Finally, as discussed in the last Response, while *Engelson* discloses a portable computer 235, *Engelson* does not teach or suggest that the portable computer independently: (i) stores medication data read from a first label and patient data read from a second label and (ii) compares the medication data to the patient data. Instead, in *Engelson*, prescription data is compared to patient data by the *medical administration management module*: “[t]he data obtained then is analyzed by the medication administration management module 110.” (Col. 13, lines 49 to 50). Fig. 3 of *Engelson*, below, and col. 6, lines 52 to 54 of *Engelson*, teach that medical administration management module 110 part of care management system 30. Nowhere does *Engelson* ever hint that the data comparison could be performed at the doctor’s personal computer 235. As pointed out above, *Engelson* only discloses personal computer 235 as enabling physicians to “access” care management system 30. Thus, inherently, personal

computer 235 does not perform the functions of software module 110, that is actually part of the care management system 30.



For all of the above reasons, Applicants respectfully request that the rejection of Claims 1 and 3 to 6 under 35 U.S.C. § 102(e) over *Engelson* be withdrawn.

New claim 7 is directed to the method of claim 1, which includes causing the handheld computing device to prompt a user to manually confirm via an input device integrated with the handheld computing device that the stored medication delivery instruction from the first label should be communicated to the medication delivery device prior to communicating the stored medication delivery instruction from the first label to the medication delivery device if the handheld computing device confirms a match between the stored prescribed medication data and the stored patient data. Support for this claim is found at paragraph [0051] of U.S. Publication 2004/0104271 (the present application). *Engelson* does not disclose this step or a handheld computing device configured to perform such a step. This step would not be readily apparent to one of ordinary skill in the art in view of *Engelson*, because as discussed above, *Engelson* does not disclose any interoperation of the portable computer 235 with the care management system 30 outside of simply “accessing” the system.

New claim 8 is directed to the method of claim 1, which includes providing a second medication container containing a second prescribed medication and a second label containing data on the second prescribed medication and instruction of delivering of the second medication, the second prescribed medication data and the instruction of delivering the second medication being provided in machine readable format; the handheld computing device: (i) reading the second prescribed medication data and second medication delivery instruction from the second label and storing the second prescribed medication data and second medication delivery

instruction, (ii) comparing the stored second prescribed medication data to the stored patient data and confirming a match between the stored second prescribed medication data and the stored patient data, and (iii) communicating the stored second medication delivery instruction from the second label to the medication delivery device; and the medication delivery device storing the second medication delivery instruction and delivering the second medication to the patient. Support for this claim is found at least at paragraph [0063] of U.S. Publication 2004/0104271. *Engelson* does not disclose these steps or a handheld computing device configured to perform such steps. These steps would not be readily apparent to one of ordinary skill in the art in view of *Engelson*, because as discussed above, *Engelson* does not suggest the portable computer 235 reading anything whatsoever or doing anything but “accessing” care managements system 30.

New claim 9 is directed to the method of claim 8, which includes the handheld computing device informing a user that two medications have been scanned and prompting the user to confirm via an input device integrated with the handheld computing device whether the user intends to proceed with two medications after the handheld computing device reads the second prescribed medication data and second medication delivery instruction from the second label. Support for this claim is found at least at paragraph [0063] of U.S. Publication 2004/0104271. *Engelson* does not disclose these steps or a handheld computing device configured to perform such steps. These steps would not be readily apparent to one of ordinary skill in the art in view of *Engelson*, because as discussed above, *Engelson* does not disclose any interoperation of the portable computer 235 with the care management system 30 outside of simply “accessing” the system.

New claim 10 is directed to the method of claim 9, which includes prompting the user to indicate via the input device which of the medication and the second medication is a primary medication and which of the medication and the second medication is a secondary medication if the user confirms that the user intends to proceed with two medications. Support for this claim is found at least at paragraph [0063] of U.S. Publication 2004/0104271. *Engelson* does not disclose this step or a handheld computing device configured to perform such a step. This step would not be readily apparent to one of ordinary skill in the art in view of *Engelson*, because as discussed above, *Engelson* does not disclose any interoperation of the portable computer 235 with the care management system 30 outside of simply “accessing” the system.

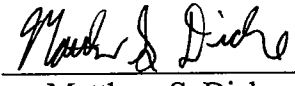
New claim 11 is directed to the method of claim 1, which includes: providing the medical device with at least two pump channels; and the handheld computing device: (i) reading data from a tag connected to a catheter associated with one of the pump channels, and (ii) confirming that the first medication is being administered to the patient by an appropriate catheter based on the data read from the tag. Support for this claim is found at least at paragraph [0063] of U.S. Publication 2004/0104271. *Engelson* does not disclose these steps or a handheld computing device configured to perform such steps. These steps would not be readily apparent to one of ordinary skill in the art in view of *Engelson*, because as discussed above, *Engelson* does not suggest the portable computer 235 reading anything whatsoever or doing anything but “accessing” care managements system 30.

New claim 12 is directed to the method of claim 1, which includes enabling a user to cancel the medication delivery instructions via selection of an input device integrated with the handheld computing device. Support for this claim is found at least at paragraph [0063] of U.S. Publication 2004/0104271. *Engelson* does not disclose this step or a handheld computing device configured to perform such a step. This step would not be readily apparent to one of ordinary skill in the art in view of *Engelson*, because as discussed above, *Engelson* does not suggest the portable computer 235 doing anything but “accessing” care managements system 30.

New claim 13 is directed to the method of claim 1, which includes enabling a user to change at least one of flow rate and volume data associated with the medication delivery instruction via an input device integrated with the handheld computing device. Support for this claim is found at least at paragraph [0062] of U.S. Publication 2004/0104271. *Engelson* does not disclose this step or a handheld computing device configured to perform such a step. This step would not be readily apparent to one of ordinary skill in the art in view of *Engelson*, because as discussed above, *Engelson* does not suggest the portable computer 235 doing anything but “accessing” care managements system 30, not suggesting the user can control the pump 90 in any manner whatsoever by portable computer 235.

Applicants respectfully submit that this case should be in condition for allowance. The Examiner is invited to contact the undersigned Attorney for the Applicants via telephone if such communication would expedite the allowance of this application.

Respectfully submitted,
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